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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/804,386	03/19/2004	Michael L. Garrison	1000-036	7250

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EXAMINER	
YABUT, DIANE D	
ART UNIT	PAPER NUMBER
3734	
MAIL DATE	DELIVERY MODE
11/12/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/804,386	GARRISON ET AL.	
	Examiner	Art Unit	
	DIANE YABUT	3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 July 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4-8 and 11-21* is/are pending in the application.

4a) Of the above claim(s) *5-7,15-17 and 19-21* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4,8,11-14 and 18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This action is in response to applicant's amendment received on 07/02/2008.

The examiner acknowledges the amendments made to the claims.

Claims 1-2, 4-8, and 11-21 are pending in this application.

Claims 5-7, 15-17, and 19-21 are withdrawn from consideration.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-2 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by **Shaknovich** (U.S. Patent No. **5,807,398**).

Claims 1-2: Shaknovich discloses a method for delivering and deploying an expandable intraluminal device **3a**, providing a delivery system comprising an elongate member **1** having proximal and distal ends and defining a lumen, the delivery system further comprising an ancillary delivery device **8** at least partially disposed in the lumen and having a means for spacing a portion of the elongate member from a wall surface of a body vessel **10**, and the expandable intraluminal medical device **3a** circumferentially disposed about a portion of the elongate member **1** (Figure 1). The distal end of the elongate member **9** is inserted into a body vessel **10**, and the distal end of the elongate member **9** is advanced through the body vessel to the desired point of treatment **11**

(Figure 2). A portion of the elongate member is spaced from a wall surface of the blood vessel at a point distal to said expandable intraluminal medical device **3a** by activating the means for spacing **8** such that an axial portion of the elongate member disposed between a proximal end of the means for spacing and a distal end of the intraluminal medical device is free of contact with the wall surface of the body vessel (Figure 2), wherein spacing a portion of the elongate member includes the expandable intraluminal device, and the expandable intraluminal medical device is deployed from the elongate member while the elongate member has been spaced from a wall surface of the body surface, again by the means for spacing **8** (Figure 5). Lastly, the elongate member is withdrawn from the body vessel (col. 4, lines 55-58).

Claim 8: Shaknovich discloses the delivery system further comprises a sheath ("protective sheath") **13** circumferentially disposed about the elongate member and movable along the elongate member, and wherein the step of deploying the expandable intraluminal medical device comprises retracting the sheath from a position about the expandable intraluminal medical device (Figure 6; col. 6, lines 3-4, col. 7, lines 43-49)

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 4 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Shaknovich** (U.S. Patent No. **5,807,398**) in view of **Kirkman** (U.S. Patent No. **6,071,263**).

Claims 4 and 11: Shaknovich discloses the claimed invention except for the means for spacing comprising a basket formed from four wires having expanded and collapsed configurations and the step of activating the means for spacing includes retracting the sheath from a position about the means for spacing.

Kirkman discloses the means for spacing comprising a basket **9** formed from four wires **12** and having expanded and collapsed configurations (Figures 2A-2B and col. 8, lines 15-19). Also, Kirkman discloses the step of activating the means for spacing includes retracting the sheath from a position about the means for spacing (col. 8, lines 10-19). Shaknovich does envision using a nitinol wire as an ancillary means of expansion (col. 9, line 64 to col. 10, line 6), and it would have been obvious to one of ordinary skill in the art to modify Shaknovich using a basket formed from four wires and using a retractable sheath about a means for spacing, as taught by Kirkman, to more efficiently contact the circumference of the blood vessel while not obstructing the fluid flow through the blood vessel and not causing clots (col. 7, lines 22-30) as well as to

protect the blood vessel from the means for spacing until expansion and to avoid the need for a second mechanism to expand the means for spacing.

5. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Shaknovich** (U.S. Patent No. **5,807,398**) in view of **Pavcnik et al.** (U.S. Pub. No. **20010039450**).

Claim 12: Shaknovich discloses the claimed steps except for the expandable intraluminal medical device comprising a venous valve.

Pavcnik et al. teach an intraluminal venous valve **43** that is deployed within the blood vessel and exerts force against the wall of the vessel and provides a partial seal against the wall, while having expandable and collapsible features (Figures 48-49 and page 1, paragraph 6, page 6, paragraph 68, and page 10, paragraph 87). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a prosthetic venous valve device, as taught by Pavcnik et al., to the device of Shaknovich, since it was known in the art that the delivery system may deploy any suitable expandable intraluminal medical device, such as a prosthetic venous valve.

6. Claims 13-14 are U.S.C. 103(a) as being unpatentable over **Shaknovich** (U.S. Patent No. **5,807,398**) in view of **Levine et al.** (U.S. Pub. No. **20040087965**).

Claims 13-14: Shaknovich discloses the claimed invention (see paragraph 3 above), except for the means for spacing, or ancillary device, comprising a basket formed from at least two wire members and having expanded and collapsed configurations such that it is movable within a lumen of an elongate member and may be distally advanced beyond an expandable intraluminal medical device, and the two wire members comprising flat wire.

Levine et al. teach an ancillary delivery device having a basket **104** in the collapsed configuration when disposed in a first lumen **114** of **102** and is in the expanded configuration when not disposed in the first lumen (Figure 4F, page 3, paragraphs 37 and 40). It would have been obvious to one of ordinary skill in the art at the time of invention to modify the means for spacing in Shaknovich by providing a basket that collapses into a first lumen and is expanded when not disposed in a first lumen, as taught by Levine et al., since it was known in the art that expandable and collapsible mechanisms are often used in deploying devices since they are readily actuated and withdrawn by the surgeon and effectively facilitate deployment of intraluminal devices.

In addition, Levine et al. teach wire members **104** comprising flat wire (page 3, paragraph 37). It would have been obvious to one of ordinary skill in the art at the time of invention to modify Shaknovich by using flat wire, as taught by Levine et al. since it

was known in the art that flat wire would provide more surface area and therefore better contact or engagement with surfaces.

7. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Shaknovich** (U.S. Patent No. **5,807,398**) in view of **Levine et al.** (U.S. Pub. No. **20040087965**), as applied to Claim 13 above, and further in view of **Pavcnik et al.** (U.S. Pub. No. **20010039450**).

Claim 18: Shaknovich and Levine et al. disclose the claimed device except for the expandable intraluminal device comprising a prosthetic venous valve.

Pavcnik et al. teach an intraluminal venous valve **43** that is deployed within the blood vessel and exerts a force against the wall of the vessel and provides a partial seal against the wall, while having expandable and collapsible features (Figures 48-49; page 1, paragraph 6; page 6, paragraph 68; page 10, paragraph 87). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a prosthetic venous valve device, as taught by Pavcnik et al., to Shaknovich and Levine et al., since it was known in the art that the delivery system may deploy any suitable expandable intraluminal medical device, such as a prosthetic venous valve.

Response to Arguments

8. Applicant's arguments filed 07/02/2008 have been fully considered but they are not persuasive.

9. Applicant generally argues that since the balloon of Shaknovich is situated directly under the stent during deployment in figure 5, the Shaknovich device is not capable of spacing an axial portion of the elongate member from the vessel wall that is disposed between the proximal end of the balloon and the distal end of the stent. However, upon further consideration by the examiner, it appears that this is only true for figure 5, which the examiner cited for the deploying step and not for the spacing step. The claim recitation suggests that the spacing step, wherein the axial portion of the elongate member is disposed between a proximal end of the balloon (means for spacing) and the distal end of the stent (intraluminal medical device) is free of contact with the wall of the body vessel, may be represented in figure 2 of Shaknovich, while the separate, independent deploying step, wherein the stent is deployed while the elongate member is being spaced from a wall surface of the body vessel by the balloon, may be represented in figure 5 of Shaknovich. In other words, the deploying step recitation "while the elongate member is being spaced from a wall surface of the body vessel," is not clearly being described as being in connection with or being dependent on the spacing step that requires that an axial portion of the elongate member disposed between the proximal end of the means for spacing and the distal end of the intraluminal medical device is free of contact with the wall surface of the body vessel.

Conclusion

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DIANE YABUT whose telephone number is (571)272-6831. The examiner can normally be reached on M-F: 9AM-4PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571) 272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Diane Yabut/
Examiner, Art Unit 3734

/Todd E Manahan/
Supervisory Patent Examiner, Art Unit 3731